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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/726,093	10/04/1996	MARTIN FUCHS	SYP-116(7783	8678

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EXAMINER

MARSCHER, ARDIN H

ART UNIT PAPER NUMBER


1631

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 08/726,093	Applicant(s) Fuchs et al.
Examiner Ardin Marschel	Art Unit 1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Oct 2, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 54, 57-62, 64-71, and 75-134 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) 57-62, 64-71, 75-82, 96-98, 100-106, 110, 112, 113, and 127 is/are allowed.

6) ☒ Claim(s) 54, 83-95, 99, 107-109, 111, 114, 116, 119-126, 128, 129, 131, 133, and 134 is/are rejected.

7) ☒ Claim(s) 115-118, 130, and 132 is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☒ Interview Summary (PTO-413) Paper No(s) 37

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

20) ☒ Other attachment for PTO-948

Applicants' arguments, filed 10/2/01, have been fully considered but they are not persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a Substitutre PTO Form 948 was mailed with Paper No. 4 on 6/2/97. Due to the above notification Applicant is required to submit acceptable Formal drawings within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Claims 54, 86-95, 119-122, 124, 128, 131, and 134 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 54 has been amended to require that the PNA-particle probe cited therein be mobilizable within the electrophoretic

separation channel. This limitation contains NEW MATTER. This limitation indicates that electrophoretic mobility is present in said channel regarding said PNA-particle probe conjugate. Consideration of the instant disclosure as filed has failed to reveal a written description of this type of electrophoretically mobile conjugate. Applicants have pointed to the instant specification at pages 11, 13, 14, 27, 28, and in examples and figures for support for this claim amending. On said page 11, lines 9-24, hybridized PNA probe/DNA complex has a mobility different from unbound probe and single stranded nucleic acids and that the neutral PNA probe will not migrate in the gel. No particle content to the PNA probe is disclosed therein thus lacking support for claim 54 with an electrophoretically mobilizable PNA-particle type of probe. The description of mobility of the PNA probe/DNA complex implies that the PNA probe does not prevent electrophoretic mobility in the electrophoretic medium or gel. Since the electrophoretic gel mobility is clearly responsive to complex size, consideration of an added particle content would be required and is not described, however, on said page 11. Similarly, the other pages etc. have not been found to contain consideration of PNA-particle mobilizability in an electrophoretic gel or medium for size discrimination and thus also do not support this type of claim amending as performed instantly. This therefore supports this rejection based on NEW

MATTER. Claims dependent directly or indirectly from claim 54 also contain this NEW MATTER due to their dependence.

Claims 120, 128, and 131 contain NEW MATTER which has not been found as filed regarding intersection of injection and electroseparation channels.

Claims 119-122 and 124 contains NEW MATTER which has not been found as filed regarding the practice of denaturation conditions which disfavor DNA-DNA hybrids specifically.

Claim 134 contains NEW MATTER which has not been found as filed regarding the practice of disposable microchips.

Claim 99 is rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 99 the phrase "the particle" lacks antecedent basis in claim 57. The word "the" in said phrase indicates a specific particle in claim 57, which, however, lacks citation of any particle. Clarification via clearer claim wording is requested.

Claims 83-85, 107-109, 111, 114, and 116 are rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

The detectable moiety limitations of claims 83-85 appear to

already be present in claim 58 from which they depend in that modification and/or binding of a detectable moiety is apparently the same material as already required in claim 58. Therefore, claims 83-85 do not further limit claim 58. This same issue is present in claims 107-109 versus claim 57 as well as in claims 111 and 114 versus claim 71, as well as 116 versus claim 115.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 123-126, 129, and 133 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Rose (Anal. Chem. 65:3545 [1993]).

Rose discloses the practice of capillary electrophoresis of PNA-ODN or PNA-oligodeoxynucleotide complexes versus uncomplexed oligomers as summarized in the abstract and the disclosure as a whole. The preincubation or premixing of complexes is disclosed specifically on page 3549, second column, first full paragraph, as also required in instant claims 123 and 125. PNA-ODN hybrid detection is shown in Rose on page 3549 in Figure 7. The capillary of the reference as described on page 3546 in the

"EXPERIMENTAL SECTION" is small and thus also anticipates the instant microchip limitations.

The disclosure is objected to because of the following informalities:

In claim 115 there are improper periods in the part designations such as "a." etc. Periods are permitted within claims only at the end and at abbreviations. Claims 116-118 are included hereinunder due to the claim 115 informality.

Appropriate correction is required.

Claims 130 and 132 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 57-62, 64-71, 75-82, 96-98, 100-106, 110, 112, 113, and 127 are allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)305-3014 or (703)308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524.

December 14, 2001

Andin H. Marschel
ANDIN H. MARSCHEL
PATENT EXAMINER